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(12) **United States Patent**
Krishna et al.(10) **Patent No.:** **US 7,598,343 B1**(45) **Date of Patent:** ***Oct. 6, 2009**(54) **PHARMACEUTICAL FORMULATIONS OF BIVALIRUDIN AND PROCESSES OF MAKING THE SAME**2008/0268032 A1 10/2008 Maggio
2008/0287650 A1 11/2008 Tovi et al.
2009/0062511 A1 3/2009 Palte et al.(75) Inventors: **Gopal Krishna**, Parsippany, NJ (US);
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WO WO 2007/149096 12/2007(73) Assignee: **The Medicines Company**, Parsippany, NJ (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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Angiomax® U.S. Prescribing Information, Dec. 6, 2005.(21) Appl. No.: **12/180,551***Primary Examiner*—Cecilia Tsang*Assistant Examiner*—Julie Ha(22) Filed: **Jul. 27, 2008**(74) *Attorney, Agent, or Firm*—Frommer Lawrence & Haug LLP; Sandra Kuzmich; Russell A. Garman(51) **Int. Cl.****A61K 38/55** (2006.01)
C07K 7/08 (2006.01)
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C07K 1/04 (2006.01)
C07K 14/00 (2006.01)(57) **ABSTRACT**(52) **U.S. Cl.** **530/325**; 530/324; 530/333; 530/334; 530/335; 514/13Pharmaceutical batch(es) or pharmaceutical formulation(s) comprising bivalirudin as the active ingredient, and a method of preparing the pharmaceutical batch(es) or pharmaceutical formulation(s). The pharmaceutical batch(es) or pharmaceutical formulation(s) may have a maximum impurity level of Asp⁹-bivalirudin that does not exceed about 0.6%. Also, the pharmaceutical batch(es) or pharmaceutical formulation(s) may have a reconstitution time that does not exceed about 42 seconds. The method of preparing the pharmaceutical batch(es) or pharmaceutical formulation(s) may comprise dissolving bivalirudin in a solvent to form a first solution, efficiently mixing a pH-adjusting solution with the first solution to form a second solution in which the pH-adjusting solution may comprise a pH-adjusting solution solvent, and removing the solvent and the pH-adjusting solution solvent from the second solution.(58) **Field of Classification Search** None
See application file for complete search history.(56) **References Cited**

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